General

Guideline Title

ACR Appropriateness Criteria® stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women.

Bibliographic Source(s)

Moy L, Newell MS, Bailey L, Barke LD, Carkaci S, D'Orsi C, Goyal S, Haffty BG, Harvey JA, Hayes MK, Jokich PM, Lee SJ, Mainiero MB, Mankoff DA, Patel SB, Yepes MM, Mahoney MC, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 12 p. [60 references]

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Recommendations

Major Recommendations

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

ACR Appropriateness Criteria®

Clinical Condition: Stage I Breast Cancer: Initial Workup and Surveillance for Local Recurrence and Distant Metastases in Asymptomatic Women

Variant 1: Newly diagnosed. Initial workup. Rule out metastases.

Radiologic Procedure	Rating	Comments	RRL*
Rule Out Bone Metastases			
Tc-99m bone scan whole body	1		
Radiographic survey whole body	4		

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

Radiologic Procedure	Rating	Comments	RRL*
FDG-PET/CT whole body	2		
Rule Out Thoracic Metastases			
X-ray chest	1		
CT chest without contrast	2		
CT chest with contrast	2		
CT chest without and with contrast	2		
FDG-PET/CT whole body	2		
Rule Out Liver Metastases			
CT abdomen without contrast	2		
CT abdomen with contrast	2		
CT abdomen without and with contrast	2		
US abdomen	2		O
MRI abdomen without contrast	2		O
MRI abdomen without and with contrast	2		O
FDG-PET/CT whole body	2		
Rule Out Brain Metastases			
MRI brain with and without contrast	2		O

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation

Radiologic Procedure	Rating	Comments	RRL*
MRI head without and with contrast	2		0
CT head without contrast	1		
CT head with contrast	1		
CT head without and with contrast	1		
FDG-PET/CT whole body	2		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 2: Surveillance. Rule out metastases.

Radiologic Procedure	Rating	Comments	RRL*
Rule Out Bone Metastases			
Tc-99m bone scan whole body	1		
X-ray radiographic survey whole body	1		
FDG-PET/CT whole body	1		
Rule Out Thoracic Metastases			
X-ray chest	1		
CT chest without contrast	1		
CT chest with contrast	1		
CT chest without and with contrast	1		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative

FDG-PET/CT whole body	1		
Rule Out Liver Metastases			
CT abdomen without contrast	1		
CT abdomen with contrast	1		
CT abdomen with and with contrast	1		
US abdomen	1		O
MRI abdomen without contrast	1		O
MRI abdomen without and with contrast	1		O
FDG-PET/CT whole body	1		
Rule Out Brain Metastases			
MRI head without contrast	1		O
MRI head without and with contrast	1		O
CT head without contrast	1		
CT head with contrast	1		
CT head without and with contrast	1		
FDG-PET/CT whole body	1		

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate

*Relative Radiation Level

Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Variant 3: Surveillance. Rule out local recurrence.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic bilateral	9	Mammography may be designated as a diagnostic examination in patients with prior breast conserving therapy, even if asymptomatic. Frequency of imaging and duration of diagnostic surveillance may vary by institution, based on local protocol.	
Mammography screening	8	Patients with prior breast conserving therapy may be returned to routine screening at some point, dependent upon institutional protocol.	
MRI breast without and with contrast bilateral	5	In selected patients, depending on risk assessment. May also be used as an adjunct tool in cases of scar versus recurrence. Should be performed in addition to, not as a replacement for, mammography. See statement regarding contrast in text below under "Anticipated Exceptions."	O
US breast bilateral	5	As an adjunct screening alternative to MRI, in selected patients, if MRI is contraindicated. Should be performed in addition to, not as a replacement for, mammography.	O
MRI breast without contrast bilateral	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

The incidence of breast cancer has increased with more than 200,000 women diagnosed with invasive carcinoma yearly. Fortunately, breast cancer mortality has decreased due to advances in screening and improved treatment. As the proportion of women diagnosed with early-stage breast cancer increases, so too does the population of breast cancer survivors, emphasizing the importance of follow-up care for these women. The premise for intense monitoring in breast cancer survivors is that the detection of an early recurrence, prior to the development of symptoms, will allow for earlier treatment and can improve overall survival. However, randomized controlled trials have found that routine testing for distant metastatic disease provides no benefit in survival or health-related quality of life, and an intensive approach to surveillance is costly. Moreover, although many physicians and patients favor intensive initial workup and surveillance, patients overestimate the value of laboratory and imaging studies and may incorrectly perceive the significance of a normal test.

Initial Workup

This appropriateness guideline criteria segment addresses the initial imaging workup of women with stage I breast carcinoma, specifically regarding

which imaging tests should be done to rule out unexpected metastatic disease.

Skeletal Metastases

Radionuclide scanning is more effective than conventional radiography for detecting skeletal metastases because radionuclide scans have higher sensitivity and can survey the entire skeleton in one examination. However, several investigations have revealed that bone scanning is not useful in stage I breast carcinoma because of its low yield and lack of proven effect on management or survival.

A large nonrandomized clinical study in Italy confirmed the lack of value of regular preoperative radiography and radionuclide bone scanning performed on stage I asymptomatic breast cancer patients. Only 1 of 633 patients with stage I disease had metastatic bone disease detected. Several other nonrandomized clinical studies have also documented the low yield and lack of utility of radionuclide bone scanning for patients with stage I breast carcinoma. Despite the low yield of bone scans, many clinicians order baseline bone scans for comparison with subsequent scans performed when patients develop symptoms or convert to an abnormal routine scan. In fact, routine baseline bone scans are unlikely to be useful in stage I disease because few patients will convert to positive scans. Also, earlier detection of metastases does not reduce overall mortality. Furthermore, several studies have reported false-positive scans when screening for metastases in asymptomatic patients.

The use of positron emission tomography (PET) combined with computed tomography (CT) in the initial staging of early-stage primary breast cancer is not well defined. It is uncertain whether PET/CT will serve as a replacement for current imaging technologies.

A retrospective study of 163 women with suspected metastatic breast cancer showed high concordance between PET/CT and bone scan in detecting bony metastases. Their results support the use of PET/CT in detecting osseous metastases and suggest that PET/CT may render bone scintigraphy unnecessary. Another study compared fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG)-PET/CT and bone scintigraphy for detection of bone metastases in breast cancer in 132 lesions. The authors concluded that on a lesion basis whole-body PET/CT is more sensitive and equally specific for the detection of bone metastases compared with bone scintigraphy. Similarly, another study showed that PET/CT is significantly more accurate than bone scintigraphy for detecting bony metastases from breast and prostate cancers. Although PET/CT is more sensitive with similar specificity to scintigraphy, PET/CT is not routinely indicated for women with stage I breast cancer due to the very low incidence of metastatic disease.

Lung Metastases

Methods for detecting lung metastases include conventional chest radiography and CT. Because of its relatively low cost, conventional chest radiography is considered the most reasonable approach for detecting unsuspected disease, as a baseline for monitoring, and for routine follow-up. No information is available regarding whether PET/CT offers an advantage over current methods for detecting lung metastases.

Despite its relatively low cost, investigators have questioned the use of routine chest radiography in patients with breast cancer, especially those with stage I disease. One problem is its low yield, reported to be <0.5% in asymptomatic women who had routine chest radiographs after the diagnosis of stage I breast carcinoma. In a study of 412 women with newly diagnosed breast cancer, chest radiograph only showed metastasis in women previously classified as having stage III disease. Furthermore, false-positive chest radiographs can lead to expensive diagnostic workups. Two large Italian randomized control studies failed to show a significant outcome benefit when routine chest radiography was used to detect metastases earlier.

A recent retrospective study investigated the value of preoperative chest CT in detecting lung and liver metastases among 1,703 patients. Abnormal CT findings, in the lung or liver, were found in 266 patients (15.6%). Only 26 patients (1.5% of all patients and 9.8% of patients with abnormal CT findings) had true metastases. Only one patient with stage I disease had a true metastasis. They concluded that routine preoperative chest CT was not useful in detecting asymptomatic liver and lung metastasis in patients with early breast cancer.

Liver Metastases

It is rarely indicated to perform imaging to detect hepatic metastases in patients with stage I disease. Although liver metastases are not as common as lung or bone metastases, the appearance of liver metastases is associated with the worst prognosis. Ultrasound (US) can identify liver metastases ≥2 cm, and it is often used to localize these lesions for biopsy. No information is available regarding whether PET/CT offers an advantage over current methods for detecting liver metastases.

As with screening for bone and lung metastases, the yield of screening with radionuclide scans or US to detect asymptomatic liver metastases is low. A study showed the yield for detecting metastases using radionuclide scans or US to be <0.5%. A review of four studies evaluating a total of 423 women with stage I breast carcinoma found on liver US that no women had metastatic lesions. In a study of 412 women with newly diagnosed breast cancer, liver US only showed metastasis in women previously classified as having stage III disease. Large randomized control studies have failed to show a benefit from screening for liver metastases with US.

In the retrospective study described above, the sensitivity, specificity, and positive predictive value of CT were 100%, 97.6%, and 18.4%, respectively, for liver metastasis. Although CT and magnetic resonance imaging (MRI) may show more lesions than radionuclide scanning or US, there is no evidence in the literature that routine imaging of the liver with either of the more sensitive modalities has clinical utility in asymptomatic patients with breast carcinoma.

Brain Metastases

Breast cancer is second only to lung carcinoma as a cause of intracerebral and orbital metastases, but few patients have brain metastases at the time of breast cancer diagnosis, particularly when the tumor is detected at stage I. One review of patients with breast cancer at all stages concluded that radionuclide brain scanning and CT failed to identify brain metastases in the absence of neurologic symptoms. A recent study prospectively explored the incidence of brain metastases during and after adjuvant trastuzumab administration in 258 patients with early-stage human epidermal growth factor receptor 2 positive (HER2+) breast carcinoma. They concluded that brain metastases are rare during adjuvant treatment and that brain CT screening is not justified in asymptomatic patients with early HER2+ breast carcinoma.

Because of its greater sensitivity, MRI has largely replaced CT for detecting and evaluating brain lesions. Gadolinium-enhanced MRI increases the number of suspected cerebral metastases that can be detected. Contrast-enhanced MRI has also been shown to be superior to double-dose delayed CT for detecting brain metastases. However, no studies suggest any usefulness to routine imaging with any modality for detecting cerebral metastases in asymptomatic women with breast cancer.

Surveillance

The most widely accepted guidelines regarding the surveillance of asymptomatic women with a history of breast cancer are from 2 national organizations: the American Society of Clinical Oncology (ASCO) and the National Comprehensive Cancer Network (NCCN). Both organizations state that routine surveillance with an annual mammogram is the only imaging test that should be performed to detect an in-breast recurrence or a new primary breast cancer. Several observational studies concluded that surveillance mammography detected locoregional recurrence and may reduce breast cancer mortality.

Local Recurrence

Local recurrence is defined as the return of cancer to the breast, lymph nodes, or chest wall after treatment. Most local recurrences occur within the first 5 years after diagnosis. The best predictor of local recurrence is whether the tumor margins contain cancer cells. The likelihood of local recurrence is lower when the tumor margins are negative. The risk of recurrence also depends on the status of the lymph nodes. Fortunately, most women are diagnosed with early-stage breast cancer, and the likelihood of local recurrence in 5 years for node-negative disease is 6.7%. If the lymph nodes are positive, the chance is 11%. The risk of local recurrence with lumpectomy plus radiation therapy can be lowered with chemotherapy and adjuvant hormonal therapy after surgery.

With mastectomy, the best predictor of local recurrence is how far the cancer has spread in the lymph nodes. The chance of local recurrence in 5 years is about 6% for women with negative lymph nodes. If 1 to 3 lymph nodes are positive, the chance of local recurrence in 5 years is about 16%. Radiation therapy can reduce this risk to about 2%.

Mammography is the imaging study used to follow women with a history of breast cancer. The role of breast MRI in screening women with a history of breast cancer is still being investigated. In 2007 the American Cancer Society published its guidelines for breast cancer screening with MRI as an adjunct to mammography. These guidelines state that in women with a personal history of breast cancer and no other risk factor, there is insufficient evidence to recommend for or against breast MRI. A group of researchers found a cancer yield of (17/144) 12% in women with a personal history of breast cancer using screening MRI. High-risk women with prior lumpectomy and a very strong family history may be considered for MRI screening. See the National Guideline Clearinghouse (NGC) summary American College of Radiology (ACR) Appropriateness Criteria® breast cancer screening.

Distant Recurrence (Metastasis)

Metastasis is the main cause of breast cancer death. The risk of distant recurrence is the same for women who undergo lumpectomy and radiation therapy or women who have a mastectomy. The most common sites for distant metastases from breast carcinoma are the skeleton, lung, liver, and brain. Surveys of patients with breast cancer indicate that most of them prefer an intensive follow-up to detect asymptomatic disease, including metastases. Surveys of physicians indicate that most of them also favor intensive surveillance programs in asymptomatic patients. However, because of cost constraints there should be a reasonable expected effect on patient management and outcome when imaging examinations are ordered on asymptomatic patients. In a review by the Cochrane Collaboration of 4 randomized, controlled clinical trials that included 3,055 women, a group of authors found no difference in overall or disease-free survival rates for women who underwent intensive radiologic and laboratory testing compared with those managed with clinical visits and mammography. They concluded that a regular physical and yearly

mammogram is as effective as more intense methods of examination in detecting recurrent breast cancer.

Two multicenter randomized prospective clinical trials were performed in Italy in the 1980s in asymptomatic breast cancer survivors. One study randomized 1,320 women into a study group that would undergo "intensive surveillance" and a control group having only tests that were ordered as a result of subsequent clinical findings uncovered at routine medical visits. The intensive surveillance included radionuclide bone scanning, chest radiography, and liver US. The study, which included 739 node-negative women, found that metastases of all kinds were detected only an average of 1 month earlier in the intensive surveillance group. The earlier detection of these metastases had no significant effect on overall survival.

A second large clinical trial in Italy randomized 1,243 women into "intensive" and "clinical" follow-up protocols to determine whether early detection of bone and intrathoracic metastases was effective in reducing mortality in the intensive follow-up group. Fifty-two percent of the women in the latter study were node-negative. Although more bone and lung metastases were found in the intensive follow-up group, there was no significant difference in the overall 5-year survival rates between the 2 groups.

As discussed above, national guidelines advise against routine surveillance testing (at regular predefined intervals), including routine blood tests, blood tests for tumor markers, chest radiographs, bone scans, liver US, abdominal CT scans, and PET/CT scans. However, clinical practices often do not adhere to these guidelines. Using the Surveillance, Epidemiology, and End Results (SEER) Medicare data, a group of researchers studied 44,591 women who were diagnosed with stage I/II breast cancer from 1992 to 1999 and followed through 2001. They found that women receiving care from medical oncologists had substantially higher rates of testing with more bone scans, tumor antigen tests, chest radiographs, and other chest/abdominal imaging than women followed by their primary health provider. Overall, the rates of testing decreased over time. Rates of tumor antigen testing and chest radiographs decreased faster than chest/abdominal imaging.

One study recently evaluated the use of high technology radiologic imaging (HTRI) for surveillance after curative treatment for early-stage breast cancer. Using the SEER-Medicare data, they identified 25,555 women who were diagnosed with stage I/II breast cancer between 1998 and 2003 who survived more than 48 months. Over time, the use of CT, bone scans, breast MRI, and PET increased from 34% of women diagnosed in 1998 to 43% in women diagnosed in 2003. Forty percent of their cohort had at least one advanced imaging examination, and 30% had CT scans. Factors associated with HTRI use were women age <80, higher comorbidity index, stage II disease, and more recent diagnosis. Another group of researchers found similar results when they reviewed the preoperative use of advanced imaging modalities in early-stage breast cancer. Using the SEER Medicare data from 1992 to 2005, the authors identified 67,874 stage I/II breast cancer patients. Approximately 19% (n=12,740) had preoperative advanced imaging. The proportion of patients having CT scans, PET scans, and brain MRI scans increased from 5.7% to 12.4% (P<.0001), 0.8% to 3.4% (P<.0001), and 0.2% to 1.1% (P=.008), respectively, from 1992 to 2005. Bone scans declined from 20.1% to 10.7% (P<.0001). They concluded that greater adherence to current guidelines is warranted.

Refer to the original guideline document for results from other studies and a discussion of quality-of-life issues.

Summary

- Given the lack of difference in survival or quality of life, there is little justification for imaging to detect or rule out metastasis in asymptomatic women with newly diagnosed stage I breast cancer.
- Women and health care professionals generally prefer intensive follow-up after a diagnosis of breast cancer. Women with other risk factors that increase their lifetime risk for breast cancer may warrant evaluation with breast MRI. However, quality-of-life is similar for women who undergo intensive surveillance compared with those who do not.
- ASCO and NCCN guidelines state that annual mammography is the only imaging examination that should be performed to detect a localized breast recurrence in asymptomatic patients; more imaging may be needed if the patient has locoregional symptoms (e.g., palpable abnormality).
- There are no survival differences between women who obtain intensive screening and surveillance with imaging and laboratory studies compared with women who only undergo testing due to the development of symptoms or findings on clinical examinations.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the ACR Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- CT, computed tomography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography
- MRI, magnetic resonance imaging
- Tc, technetium
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Stage I breast cancer

Guideline Category

Evaluation

Screening

Clinical Specialty

Internal Medicine

Nuclear Medicine

Obstetrics and Gynecology

Oncology

Radiology

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of radiologic examinations for initial workup and surveillance for local recurrence and distant metastases in asymptomatic women with stage I breast cancer

Target Population

Asymptomatic women with stage I breast cancer

Interventions and Practices Considered

1. X-ray
    - Radiographic survey whole body
    - Chest
2. Technetium (Tc)-99m bone scan whole body
3. Computed tomography (CT)
    - Chest without and with contrast
    - Chest with contrast
    - Chest without contrast
    - Abdomen without and with contrast
    - Abdomen with contrast
    - Abdomen without contrast
    - Head without and with contrast
    - Head with contrast
    - Head without contrast
4. Magnetic resonance imaging (MRI)
    - Abdomen without and with contrast
    - Abdomen without contrast
    - Head without and with contrast
    - Head without contrast
    - Breast without contrast bilateral
    - Breast without and with contrast bilateral
5. Fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography (FDG-PET)/CT whole body
6. Ultrasonography (US)
    - Abdomen
    - Breast, bilateral
7. Mammography
    - Diagnostic bilateral
    - Screening

Major Outcomes Considered

- Utility of radiologic examinations in staging and detection of recurrence and metastases
- Quality of life
- Risk of recurrence
- Overall, disease-free, and 5-year survival rate
- Rates of testing
- Accuracy, sensitivity, and specificity of radiologic examinations
- False-positive and false-negative rates

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
c. The study is an expert opinion or consensus document.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel’s final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for initial workup and surveillance for local recurrence and distant metastases in asymptomatic women with stage I breast cancer

Potential Harms

- Several studies have reported false-positive scans as a problem encountered when screening for metastases in asymptomatic patients.
- False-positive chest radiographs can lead to expensive diagnostic workups.
- Occasionally, the additional imaging studies will generate false-positive examinations. These findings may lead to follow-up imaging studies, biopsies, and possibly surgery. One study concluded that clinicians have sold their patients on the promise of advanced imaging and neglected to educate them about the detrimental effects of excess exposure to radiation, additional testing brought about by chasing false-positive results, or the anxiety related to these studies. Ordering advanced imaging studies may provide patients with short-term reassurance but seldom allays long-term fears of recurrence that are ubiquitous in cancer survivors.

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based

contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Identifying Information and Availability

Bibliographic Source(s)

Moy L, Newell MS, Bailey L, Barke LD, Carkaci S, D'Orsi C, Goyal S, Haffty BG, Harvey JA, Hayes MK, Jokich PM, Lee SJ, Mainiero MB, Mankoff DA, Patel SB, Yepes MM, Mahoney MC, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 12 p. [60 references]

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Not applicable: The guideline was not adapted from another source.

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Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

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Panel Members: Linda Moy, MD (*Principal Author*); Mary S. Newell, MD (*Co-author and Panel Vice-chair*); Lisa Bailey, MD; Lora D. Barke, DO; Selin Carkaci, MD; Carl D'Orsi, MD; Sharad Goyal, MD; Bruce G. Haffty, MD; Jennifer A. Harvey, MD; Mary K. Hayes, MD; Peter M. Jokich, MD; Su-Ju Lee, MD; Martha B. Mainiero, MD; David A. Mankoff, MD, PhD; Samir B. Patel, MD; Monica M. Yepes, MD; Mary C. Mahoney, MD (*Panel Chair*)

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

Guideline Availability

Electronic copies of the updated guideline: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. 2013 Apr. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria® stage I breast cancer: initial workup and surveillance for local recurrence and distant metastases in asymptomatic women. Evidence table. Reston (VA): American College of Radiology; 2014. 22 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

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